UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ACUITAS THERAPEUTICS INC., *Plaintiff*, vs. GENEVANT SCIENCES GMBH, and ARBUTUS BIOPHARMA CORP., *Defendants*.	Case No. 1:22-cv-02229-MKV

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

Raymond N. Nimrod
Isaac Nesser
Matthew D. Robson
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
T: 212-849-7000

Kevin P.B. Johnson
QUINN, EMANUEL, URQUHART & SULLIVAN, LLP
555 Twin Dolphin Drive, 5th Floor
Redwood Shores, CA 94065
T: 650-801-5000

Sandra Haberny (*pro hac vice* granted)
QUINN, EMANUEL, URQUHART & SULLIVAN, LLP
865 S. Figueroa Street, 10th Floor
Los Angeles, CA 90017
T: 213-443-3000

Attorneys for Defendant Genevant Sciences GmbH

Daralyn J. Durie (*pro hac vice* granted)
Eric C. Wiener (*pro hac vice* granted)
DURIE TANGRI LLP
217 Leidesdorff Street
San Francisco, CA 94111
T: 415-362-6666

Kira A. Davis
DURIE TANGRI LLP
953 E. 3rd Street
Los Angeles, CA 90013
T: 213-992-4499

Attorneys for Defendant Arbutus Biopharma Corp.

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. SUMMARY OF ARGUMENT 1

III. BACKGROUND 5

IV. LEGAL STANDARDS 7

V. ARGUMENT 8

A. The Court Should Dismiss The Amended Complaint For Lack Of Subject Matter Jurisdiction 8

1. The Amended Complaint Fails To Plead An Actual Controversy Between Acuitas And Defendants 8

a. Reason 1: Acuitas Has Not Pled Any Affirmative Act Of Patent Enforcement By Defendants Directed At Acuitas 8

b. Reason 2: Acuitas Has Not Pled Any Legally Cognizable Injury-In-Fact 10

c. Reason 3: Acuitas Has Not Shown That Acuitas And Defendants Have Adverse Legal Interests 13

d. Reason 4: Acuitas Has Not Shown That There Is A Substantial Controversy Of Sufficient Immediacy And Reality 14

2. Acuitas's Attempt To Rely On Its Alleged Supplier-Customer Relationship With Pfizer/BNT Fails To Establish Jurisdiction 15

a. Acuitas's Indemnity Theory Fails To Establish Jurisdiction 15

b. Acuitas's Indirect Infringement Theory Fails To Establish Jurisdiction 18

c. Acuitas's Supplier-Customer Argument Fails For The Separate Reason That There Is No Actual Controversy Between Defendants And Pfizer/BNT, So Acuitas Cannot Step Into Pfizer/BNT's Shoes To Defend Them 22

B. The Court Should Exercise Its Discretion To Decline To Hear Acuitas's Request For Declaratory Judgment 24

VI. CONCLUSION 25

TABLE OF AUTHORITIES

Page

Cases

Adenta GmbH v. OrthoArm, Inc.,
501 F.3d 1364 (Fed. Cir. 2007)..... 8

Adobe Sys. Inc. v. Kelora Sys. LLC,
No. 11-3938, 2011 WL 6101545 (N.D. Cal. Dec. 7, 2011)..... 9

Allied Mineral Products, Inc. v. Osmi, Inc.,
870 F.3d 1337 (Fed. Cir. 2017)..... 9, 12, 22

Alnylam Pharms., Inc. v. Pfizer, Inc.,
No. 22-336 (D. Del. Mar. 17, 2022) 7, 11, 13, 14, 15, 22

Arris Group v. British Telecom. PLC,
639 F.3d 1368 (Fed. Cir. 2011)..... 13, 15, 22

Asia Vital Components Co. v. Asetek Danmark A/S,
837 F.3d 1249 (Fed. Cir. 2016)..... 12

Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off.,
653 F.3d 1329 (Fed. Cir. 2011)..... 8, 13

BroadSign Int'l, LLC v. T-Rex Prop. AB,
No. 16-cv-04586, 2018 WL 357317 (S.D.N.Y. Jan. 10, 2018) 9, 10, 18, 20

Commc'ns Test Design, Inc. v. Contec, LLC,
952 F.3d 1356 (Fed. Cir. 2020)..... 24

EMC Corp. v. Norand Corp.,
89 F.3d 807 (Fed. Cir. 1996)..... 25

Gordon v. Target Corp.,
No. 20-CV-9589, 2022 WL 836773 (S.D.N.Y. Mar. 18, 2022) 6

Hesse v. Godiva Chocolatier, Inc.,
463 F. Supp. 3d 453 (S.D.N.Y. 2020)..... 11

Intel Corp. v. Future Link Sys., LLC,
No. 14-377, 2015 WL 649294 (D. Del. Feb. 12, 2015)..... 16, 17, 18

LaserDynamics, Inc. v. Quanta Comp., Inc.,
694 F.3d 51 (Fed. Cir. 2012)..... 14

MedImmune, Inc. v. Genentech, Inc.,
549 U.S. 118 (2007) 7, 13

Microchip Tech., Inc. v. Chamberlain Group, Inc.,
441 F.3d 936 (Fed. Cir. 2006) 13

Microsoft Corp. v. DataTern,
755 F.3d 899 (Fed. Cir. 2014) 16, 18, 19, 20, 21, 22

Microsoft Corp. v. SynKloud Techs., LLC,
484 F. Supp. 3d 171 (D. Del. 2020) 8, 16, 18

ModernaTx, Inc. v. Arbutus Biopharma Corp.,
18 F.4th 1364 (Fed. Cir. 2021) 24

Organic Seed Growers & Trade Ass'n v. Monsanto Co.,
851 F. Supp. 2d 544 (S.D.N.Y. 2012) 10

Prasco, LLC v. Medicis Pharm. Corp.,
537 F.3d 1329 (Fed. Cir. 2008) 10, 11

Proofpoint, Inc. v. InNova Pat. Licensing, LLC,
No. 5:11-CV-02288, 2011 WL 4915847 (N.D. Cal. Oct. 17, 2011) 18

SanDisk Corp. v. STMicroelectronics, Inc.,
480 F.3d 1372 (Fed. Cir. 2007) 23

SRI Intern., Inc. v. Advanced Technology Laboratories, Inc.,
127 F.3d 1462 (Fed. Cir. 1997) 23

Statutory Authorities

35 U.S.C. § 271(b) 19

35 U.S.C. § 271(c) 19

35 U.S.C. § 287(a) 6, 22

Rules and Regulations

Fed. R. Civ. P. 12(b)(1) 1

I. INTRODUCTION

Acuitas Therapeutics Inc. ("Acuitas") initiated this declaratory judgment action against Genevant Sciences GmbH ("Genevant") and Arbutus Biopharma Corp. ("Arbutus" and, together with Genevant, "Defendants") on March 18, 2022, and filed a First Amended Complaint ("Amended Complaint") on September 6, 2022. Acuitas seeks declarations that the manufacture, use, offer to sell, and sale of the COVID-19 vaccine COMIRNATY® ("Comirnaty") made and sold by nonparties Pfizer Inc. ("Pfizer") and BioNTech SE ("BNT") does not infringe any claim of nine patents owned by Arbutus and licensed to Genevant ("Defendants' Patents") and that Defendants' Patents are invalid. The Court should dismiss the Amended Complaint under Fed. R. Civ. P. 12(b)(1) because Acuitas has failed to meet its burden to show that there is an actual controversy between Acuitas and Defendants. Even if Acuitas could somehow establish subject matter jurisdiction, the Court should use its discretion to decline to hear Acuitas's request for declaratory judgment for at least two independent reasons. *First*, this suit runs the serious risk of creating a multiplicity of actions regarding the same vaccine and the same patents, thereby serving no useful purpose. *Second*, pending discussions between Genevant[1] and Pfizer/BNT regarding a potential license for Comirnaty could moot this suit at any time, resulting in the Court having expended its time and resources unnecessarily.

II. SUMMARY OF ARGUMENT

Acuitas's Amended Complaint is perhaps most notable for what it does not allege. It does not allege that Defendants have ever sent Acuitas any communication regarding Comirnaty. It does not allege that Defendants have ever accused Acuitas of infringing Defendants' Patents, whether directly or indirectly. It does not allege that Acuitas makes or sells Comirnaty. It does

[1] Genevant has the authority by contract to license Defendants' Patents in this situation.

not allege that Defendants have ever tried to stop Acuitas from licensing or supplying any lipid or lipid nanoparticle ("LNP") technology to Pfizer/BNT for use in Comirnaty. And it does not allege that Pfizer/BNT have stopped paying Acuitas royalties on Comirnaty, or that Acuitas has lost any potential business deals. These failures lead to dismissal for four independent reasons.

First, under Federal Circuit law, declaratory judgment jurisdiction in a patent case is available only where there have been affirmative acts by the patentee relating to patent enforcement that were ***directed at the specific Plaintiff***. Here, the Amended Complaint does not allege that Defendants have taken any affirmative act whatsoever directed ***at the Plaintiff Acuitas*** regarding potential infringement by Comirnaty. Rather, Acuitas relies exclusively on two letters Defendants directed and sent to ***nonparties*** Pfizer/BNT offering to discuss a partnering arrangement to help with the vaccine and a license to Defendants' Patents. But those letters do not even mention Acuitas, much less accuse it of infringing or threaten enforcement against Acuitas.

Second, Acuitas has failed to allege any concrete injury-in-fact fairly traceable to Defendants' conduct, which is required to establish standing. Nowhere does the Amended Complaint identify any specific lost licensing opportunity, lost business deal, lost royalty, lost revenue, or any other form of concrete injury caused by Defendants' letters to Pfizer/BNT. Acuitas has been on notice for months of this deficiency, which Defendants noted in the parties' joint letter to the Court. Dkt. 36 at 4. Despite opting to amend the complaint, Acuitas still has not—presumably because it cannot—identified any concrete injury caused by the letters sent to Pfizer/BNT.

Instead, Acuitas relies on vague allegations of injury, including "concerns" raised by unidentified potential future business partners, presumably (because it is not alleged) after learning

of Defendants' letters to Pfizer/BNT. Dkt. 42, ¶ 54. But, even if such concerns could establish an injury-in-fact (they do not), such injury is certainly not fairly traceable to ***Defendants'*** conduct as required for jurisdictional purposes. Defendants sent the letters privately to Pfizer/BNT. It was ***Acuitas itself*** that exposed the letters to the public in its complaint. Simply put, if there is any injury here relating to Acuitas's potential future business partners, it is self-inflicted.

Third, Acuitas fails to meet its burden to show that it has legal interests adverse to Defendants. Defendants have never demanded that Acuitas cease licensing or supplying any lipid or LNP technology for Pfizer/BNT to use in the vaccine. Defendants' statement to ***Pfizer/BNT*** that ***they*** may require a license from Defendants does not create any adverse legal interests between Defendants and Acuitas, nor does it suggest that Acuitas must cease licensing or supplying Pfizer/BNT. Pfizer/BNT could take a license to Defendants' Patents and ***also*** continue to license Acuitas's technology for Comirnaty. Multiple licenses are common and do not create actual controversies between the various licensors—they can each obtain royalties as appropriate for the use of their inventions.

Fourth, Acuitas has not met its burden to show there is a substantial controversy of sufficient immediacy and reality to warrant a declaratory judgment. The letters to Pfizer/BNT that Acuitas relies on were sent nearly two years ago and one year ago, respectively, and neither Pfizer nor BNT (or either Defendant) has sought judicial intervention since then. Acuitas does not allege that discussions regarding a potential license have been terminated, nor have they. Acuitas has not pled anything about the state of the discussions, nor could Acuitas because it is not privy to them.

Attempting to manufacture a basis for subject matter jurisdiction despite these pleading failures, Acuitas amended its complaint to allege two new theories based on supplier-customer caselaw, namely indemnity and indirect infringement. Neither succeeds. As to indemnity, Federal

Circuit law instructs that subject matter jurisdiction cannot be based merely on potential indemnity—a plaintiff-supplier must allege that it is ***actually obligated*** to indemnify its customer. Acuitas does not allege it actually has any such indemnity obligation to Pfizer/BNT—instead Acuitas, if anything, appears to dispute that it has that obligation. Acuitas's reliance on an indirect infringement theory also fails because Defendants have never asserted that Acuitas has committed an act that contributes to or induces infringement. Acuitas's purported indirect infringement concern is based entirely on the letters to Pfizer/BNT, but those letters do not even mention Acuitas, let alone allege that Acuitas has committed any of the prerequisite acts to contribute to or induce infringement.

Lastly, even if Acuitas could somehow demonstrate subject matter jurisdiction, the Court should exercise its discretion to decline to hear this suit because it runs the serious risk of creating a multiplicity of actions regarding the same vaccine and the same patents. For example, if the Court were to determine in this action that Comirnaty infringes Defendants' Patents or that they are not invalid, Pfizer/BNT might very well on the next day file an independent action for noninfringement and invalidity and attempt to argue that, as nonparties here, they are not bound or estopped by this Court's judgment. The Court ought not waste its resources deciding the question of whether the vaccine infringes when the actual makers and sellers of the vaccine can turn around and claim they are not bound by the Court's judgment.

The Court should decline to hear this suit for the additional reason that it seeks to adjudicate issues that may never require judicial resolution given the pending discussions between Genevant and Pfizer/BNT regarding a potential license. There is no need to burden the Court with Acuitas's premature side-show action when the actual parties to the discussions have not sought judicial intervention and a license could moot this case at any time.

For these reasons, and as discussed in more detail below, this Court should dismiss the Amended Complaint for lack of subject matter jurisdiction or in the alternative exercise its discretion to decline to entertain Acuitas's suit.

III. BACKGROUND

Genevant is a technology-focused nucleic acid delivery company and a world leader in the LNP space, with the industry's most robust and expansive LNP patent portfolio and decades of expertise in nucleic acid drug delivery and development. Genevant has licensed LNP-related patents from Arbutus, which is a clinical-stage biopharmaceutical company with deep virology expertise and an unwavering focus on curing a variety of conditions. Defendants' Patents cover important aspects of LNP technology for delivering RNA to cells in the body for therapeutic effect and are generally directed to nucleic acid-lipid particles comprising specific types of lipids, sometimes in required ratios. *See, e.g.*, Dkt. 1-1 (U.S. Patent No. 8,058,069, claim 1). All the patents require both a nucleic acid (*e.g.*, mRNA) and an LNP with specific lipid types.

Genevant and BNT have a long history of collaboration on LNP-related research and development programs. In 2018, BNT licensed Defendants' Patents from Genevant, among other patents, in connection with BNT's development of therapeutics in the oncology field. That BNT agreement describes Genevant's platform as "the best lipid nanoparticle technology," confirming BNT's understanding of the value of Genevant's LNP technology. Ex. A[2] at 1.[3] This 2018 license was limited, however, to the development of certain cancer or rare disease treatments and did not cover infectious diseases, such as COVID-19.

[2] All references to "Ex. __" in this brief are to the exhibits to the Declaration of Matthew D. Robson, submitted herewith.

[3] *Available at* www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330dex1017.htm. On a Rule 12(b)(1) motion, "[c]ourts may take judicial notice of public documents or documents of public record …." *Gordon v. Target Corp.*, No. 20-CV-9589, 2022 WL 836773, at *2 (S.D.N.Y. Mar. 18, 2022).

Accordingly, on November 23, 2020, Defendants sent a letter to Pfizer/BNT asking for the opportunity to discuss a partnering arrangement that would enable Pfizer/BNT to benefit from Genevant scientists' extensive expertise with the formulation and manufacture of LNP delivery systems and welcoming discussions of licensing Defendants' patents. On October 12, 2021, Defendants sent a second letter identifying another Arbutus patent relevant to the proposed discussion. These letters also noted, under 35 U.S.C. § 287(a), that the making, using, selling, offering for sale, or importing into the United States of Comirnaty may infringe Defendants' Patents. *See* Exs. B & C.[4] The letters do not include an analysis of potential infringement (*e.g.*, they did not attach claim charts). Importantly, Defendants never sent either letter to Acuitas, nor made them public.

Following this correspondence, Genevant and BNT (acting also on behalf of Pfizer) entered into discussions regarding a potential license to Defendants' Patents for Comirnaty. These discussions are referenced in Defendants' October 2021 letter, and, in the months following that letter, the parties to the discussions agreed to terms of confidentiality covering the discussions. This agreement, made in January 2022, prohibits any entity other than Defendants and Pfizer/BNT from being privy to the discussions. That is, far from standing in the shoes of Pfizer/BNT to resolve any potential dispute with Defendants, Acuitas is prohibited from even being privy to their discussions.

Acuitas does not manufacture or sell Comirnaty. Acuitas alleges that it licenses and supplies lipids, including the ALC-315 cationic lipid, and LNPs to Pfizer/BNT. The Amended Complaint does not allege that Acuitas's license agreement with Pfizer/BNT precludes Pfizer/BNT

[4] On a Rule 12(b)(1) motion, the Court may consider documents incorporated into the complaint where, as here with respect to the two letters to Pfizer/BNT, the plaintiff relies on the materials in framing the complaint, (2) the complaint clearly and substantially references the documents, and (3) the documents' authenticity or accuracy is undisputed. *Gordon*, 2022 WL 836773, at *2.

from licensing additional LNP-related technology from others, and indeed, in a suit actually involving Pfizer, Pfizer itself has noted that BNT has licensed technology used in the vaccine from "multiple partners," of which Acuitas is only one. *Alnylam Pharms., Inc. v. Pfizer, Inc.*, No. 22-336 (D. Del. Mar. 17, 2022), Dkt. 13, ¶ 24. This is common. *See*, *e.g.*, Taorui Guan, *Evidence-Based Patent Damages*, 28 J. INTELL. PROP. L. 1, 18 (2020) ("In some industries, such as … biotechnology, one product can involve multiple patents. A product infringing the patentee's patent might therefore also apply the patents of third parties."). In this way, Pfizer/BNT are not required to license *only* Acuitas's patents or *only* Defendants' patents, but may require licenses from both Acuitas and Defendants, and potentially additional parties too. There is no inherent conflict between licensors of LNP technology. And Defendants have never asserted that Acuitas must stop licensing or supplying any lipid or LNP technology to Pfizer/BNT for use in Comirnaty.

IV. LEGAL STANDARDS

To establish subject matter jurisdiction, it is Acuitas's burden to establish that there is "a case of actual controversy" between itself and Defendants. The Supreme Court has instructed that "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). Where an action seeks a declaratory judgment regarding rights arising under patent law, Federal Circuit law controls the subject matter jurisdiction inquiry. *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364, 1368 (Fed. Cir. 2007).

V. ARGUMENT

A. The Court Should Dismiss The Amended Complaint For Lack Of Subject Matter Jurisdiction

The Amended Complaint fails to plead an actual controversy between Acuitas and Defendants. Moreover, Acuitas's attempt to rely on its alleged supplier-customer relationship with Pfizer/BNT to create an actual controversy also fails.

1. The Amended Complaint Fails To Plead An Actual Controversy Between Acuitas And Defendants

The Amended Complaint fails to establish an actual controversy between Acuitas and Defendants for four reasons, each of which is independently dispositive and compels dismissal. *First*, Acuitas has not pled an affirmative act of patent enforcement by Defendants directed at Acuitas. *Second*, Acuitas has not pled any legally cognizable injury-in-fact. *Third*, Acuitas has not shown that Acuitas and Defendants have adverse legal interests. *Fourth*, Acuitas has not shown that there is a substantial controversy of sufficient immediacy and reality.

a. Reason 1: Acuitas Has Not Pled Any Affirmative Act Of Patent Enforcement By Defendants Directed At Acuitas

A declaratory judgment plaintiff must allege "an affirmative act by the patentee related to the enforcement of his patent rights" to establish an actual controversy. *Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Off.*, 653 F.3d 1329, 1348 (Fed. Cir. 2011) (overruled on other grounds). Moreover, the patentee's affirmative acts of enforcement must be directed at the "specific plaintiffs" seeking the declaratory judgment. *Id.* at 1348; *see also Microsoft Corp. v. SynKloud Techs., LLC*, 484 F. Supp. 3d 171, 177 (D. Del. 2020) ("The patentee's affirmative acts must be ***directed at the 'specific plaintiffs'*** seeking a declaratory judgment." (citing *Molecular Pathology*)).[5] Acuitas has not pled any affirmative act of patent enforcement of Defendants'

[5] All emphases in this brief are supplied unless otherwise noted.

Patents by Defendants directed specifically at Acuitas, and thus it has failed to establish an actual controversy.

Indeed, Acuitas ***does not even allege that the Defendants ever contacted or communicated with it in any way regarding Comirnaty***. Nor is there any allegation that Defendants have threatened Acuitas with litigation, demanded a royalty from Acuitas, or demanded that Acuitas stop licensing or supplying Pfizer/BNT with any lipids or LNP technology. The circumstances here are similar to other cases where dismissal was appropriate because there was no communication whatsoever between the patentee and plaintiff regarding patent infringement. For example, in *Allied Mineral Products, Inc. v. Osmi, Inc*., the Federal Circuit affirmed dismissal of a declaratory judgment action where, as here, there were "no veiled threats of litigation or even any direct communication from [defendants] to [plaintiff]." 870 F.3d 1337, 1340 (Fed. Cir. 2017). Other courts, considering the totality of the circumstances, have likewise dismissed declaratory judgment actions where, as here, "[plaintiff] has not alleged that [defendant] has communicated with [plaintiff] at all before [plaintiff] instituted this suit." *Adobe Sys. Inc. v. Kelora Sys. LLC*, No. 11-3938, 2011 WL 6101545, at *4 (N.D. Cal. Dec. 7, 2011); *see also BroadSign Int'l, LLC v. T-Rex Prop. AB*, No. 16-cv-04586, 2018 WL 357317, at *4 (S.D.N.Y. Jan. 10, 2018) (dismissing complaint where there was "no indication of any discussion or threat of litigation against Plaintiff").

Moreover, the Amended Complaint does not allege that Defendants have ever contended or asserted that Acuitas infringes Defendants' Patents in connection with Comirnaty. The Amended Complaint is devoid of any allegation that Defendants have ever stated to Pfizer, BNT, or anyone else that Acuitas infringes Defendants' Patents. The Amended Complaint attempts to rely on the two letters Defendants sent to nonparties Pfizer/BNT but these letters ***do not even***

mention Acuitas, much less identify any act of Acuitas as infringing. Dismissal under Rule 12(b)(1) is proper where, as here, the patentee has never identified any of the plaintiff's conduct as infringing. *See Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 851 F. Supp. 2d 544, 551 (S.D.N.Y. 2012) (dismissing declaratory judgment complaint lacking any "alleg[ation] that defendants have ever demanded royalty payments from plaintiffs, identified any of plaintiffs' conduct as potentially infringing, or even initiated any contact with plaintiffs whatsoever.").

Acuitas's failure to plead any affirmative act of patent enforcement against it requires dismissal.

b. Reason 2: Acuitas Has Not Pled Any Legally Cognizable Injury-In-Fact

The Amended Complaint is also subject to dismissal because Acuitas has not alleged any legally cognizable injury-in-fact. As the Federal Circuit has instructed, to establish standing, a plaintiff must (1) "allege [] ***an injury-in-fact, i.e., a harm that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical***;" and (2) the injury-in-fact must be "'fairly traceable' to the defendant's conduct," among other things. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008). Acuitas does not come close to meeting this burden.

Acuitas Impermissibly Attempts To Rely On Alleged Harms That Are Self-Inflicted, Rather Than Being Traceable To Defendants' Conduct—The majority of Acuitas's allegations attempting to show injury-in-fact are based on the purported impact that the letters to Pfizer/BNT had or may have on potential customers in the market besides Pfizer/BNT. For example, Acuitas alleged that "[p]otential licensing partners have raised concerns about Arbutus's and Genevant's demands against Pfizer and BioNTech." Dkt. 42, ¶ 54. But, even if Acuitas's vague allegations regarding "concerns" raised by potential licensing partners were sufficient to establish an injury-in-fact (they are not), the injury would not be fairly traceable to ***Defendants'*** conduct. Defendants

sent the letters privately to Pfizer and BNT—not to any other potential licensing partner of Acuitas or to the public. It was ***Acuitas itself*** that made Defendants purported "demands" publicly available in its complaint. Simply put, if there is any injury here, it is self-inflicted. That does not suffice. *See Prasco*, 537 F.3d at 1338 (injury must be "'fairly traceable' to defendants' conduct").

Acuitas Has Not Pled A Concrete Injury—The Amended Complaint is devoid of a single allegation of a concrete injury. It identifies no specific lost licensing opportunity, lost business deal, lost royalty, lost revenue, or any other form of concrete injury. This failure is all the more telling given that Defendants specifically highlighted the lack of an allegation of any specific lost business deal or royalties in the parties' joint letter to the Court. Dkt. 36 at 4 ("Acuitas has not alleged injury-in-fact, such as the loss of specific business deals or royalties, resulting from the letters Defendants sent to Pfizer and BioNTech."). Yet, in its Amended Complaint, Acuitas still has not—presumably because it cannot—identified any specific lost business deals, royalties, or revenues.

The most Acuitas has been able to say about any effect Defendants' letters have had on its current relationship with Pfizer/BNT is they have "impact[ed] the relationship," without alleging how. Dkt. 42, ¶ 54. This tepid allegation of an "impact" falls well short of a concrete harm. To the contrary, Acuitas announced a new licensing deal ***with Pfizer*** in January 2022,[6] indicating that its business relationship with Pfizer is in fact thriving. And Acuitas's May 2022 deal with another

[6] *See* Ex. D (https://acuitastx.com/wp-content/uploads/2022/01/Acuitas-Pfizer-Agreement-Release.pdf). On a Rule 12 motion, "a court may take judicial notice of information publicly announced on a party's website, as long as the website's authenticity is not in dispute and 'it is capable of accurate and ready determination.'" *Hesse v. Godiva Chocolatier, Inc.*, 463 F. Supp. 3d 453, 463 (S.D.N.Y. 2020).

company for a license to LNP technology highlights that Acuitas's vague allegations of third-party "concerns" do not support an inference of any harm to Acuitas, much less concrete harm.[7]

Acuitas Impermissibly Attempts To Rely On 'Conjectural' And 'Hypothetical' Harms— Unable to plead a concrete injury, Acuitas attempts to rely on two categories of alleged "harms," both of which the Federal Circuit has rejected as insufficient.

First, Acuitas contends that the fear of future suits may potentially cause it future lost business. *See* Dkt. 42, ¶ 54 ("Acuitas and any company that works with Acuitas or utilizes Acuitas's LNPs or LNP technology face the risk of suit for infringement"). But the Federal Circuit has instructed that neither a "fear of a future infringement suit" nor a "fear of future lost business because of infringement threats against a customer" establish standing:

> ***[W]e have held that the fear of a future infringement suit is insufficient to confer jurisdiction***. … And in *Arris*, we noted the ***fear of future lost business because of infringement threats against a customer was, by itself, insufficient to create standing for the manufacturer.*** [Plaintiff's] fear alone does not give the district court jurisdiction.

Allied, 870 F.3d at 1341 (internal citation omitted). This is in accordance with the "bedrock rule" that the injury-in-fact requirement "cannot be met by a purely subjective or speculative fear of future harm." *Asia Vital Components Co. v. Asetek Danmark A/S*, 837 F.3d 1249, 1253 (Fed. Cir. 2016).

Second, Acuitas attempts to rely on its economic interest in clarifying whether Pfizer, BNT, or others may use Acuitas's LNP technology free and clear of Defendants' Patents. *See* Dkt. 42, ¶ 54 ("It is very important to Acuitas's business that partners and prospective partners can use the

[7] *See* Ex. E (www.prnewswire.com/news-releases/myeloid-therapeutics-enters-into-agreement-with-acuitas-therapeutics-for-lipid-nanoparticle-lnp-system-enabling-the-first-ever-delivery-of-mrna-encoded-cars-directly-to-humans-301551149.html).

licensed Acuitas LNP technology free and clear of any third-party patents."). The Federal Circuit, however, has instructed that any such economic interest is insufficient to establish jurisdiction:

> At most, ***[plaintiff] had only an economic interest in clarifying its customers' rights*** under [patentee's] patents, which may have facilitated the sale of [plaintiff's] products. [Plaintiff] perhaps would economically have benefited if its customers had no fear of suit by [patentee]. ***Such an economic interest alone, however, cannot form the basis of an "actual controversy"***….

Microchip Tech., Inc. v. Chamberlain Group, Inc., 441 F.3d 936, 943 (Fed. Cir. 2006); *see also Arris Group v. British Telecom. PLC*, 639 F.3d 1368, 1374 (Fed. Cir. 2011) (citing and quoting *Microchip* (post-*MedImmune*) for the proposition that "where [the] sole injury alleged was economic harm to [the] declaratory plaintiff caused by patentee's purported threatening of its customers, '[s]uch an economic interest alone ... cannot form the basis of an 'actual controversy' under the Declaratory Judgment Act.'").

c. Reason 3: Acuitas Has Not Shown That Acuitas And Defendants Have Adverse Legal Interests

Acuitas also has not pled facts showing that there are adverse legal interests between Acuitas and Defendants. As the Supreme Court has instructed, to establish subject matter jurisdiction there must be a substantial controversy between parties "having adverse legal interests." *MedImmune*, 549 U.S. at 127. The Federal Circuit has found that an adverse legal interest exists where a plaintiff claims the right to engage in activity without a license and the patentee contends the plaintiff requires a license. *Molecular Pathology*, 653 F.3d at 1345 (finding subject matter jurisdiction where plaintiff and defendant had "taken adverse legal positions regarding whether or not [plaintiff] can engage in [act] without infringing any valid claim").

Here, Defendants have never asserted that Acuitas must cease licensing or supplying Pfizer/BNT with lipids or LNP technology for Comirnaty or that it requires a license to Defendants' Patents. Defendants' statement that ***Pfizer/BNT may require*** a license to Defendants'

Patents simply does not create any adverse legal interests between Defendants and Acuitas. If Pfizer/BNT were to take a license to Defendants' Patents, Pfizer/BNT would not be prevented from continuing to ***also*** license Acuitas's patents. *See LaserDynamics, Inc. v. Quanta Comp., Inc.*, 694 F.3d 51, 66 (Fed. Cir. 2012). There is no allegation in the Amended Complaint suggesting to the contrary.

That Acuitas allegedly owns a patent covering some aspect of the lipids or LNP technology used in Comirnaty (perhaps the ALC-315 lipid) has no bearing on whether other aspects of the LNP technology used in the vaccine are covered by Defendants' Patents or any other patent owned by anyone else. A product like Comirnaty may use the patented technology of multiple patentees and thus require multiple licenses. *See, e.g.*, *LaserDynamics*, 694 F.3d at 66 (acknowledging products may be composed of many components "which may be separately patented, the patents often being owned by different entities."). Indeed, Pfizer has pled in the *Alnylam* suit that "BioNTech licensed technology ***from multiple partners***" in connection with the vaccine, including ALC-315 from Acuitas. Case No. 22-336, Dkt. 13, ¶ 24. There is no inherent adversity between all potential technology licensors for a complex product like Comirnaty, and Acuitas has not met its burden to show adverse legal interests.

d. Reason 4: Acuitas Has Not Shown That There Is A Substantial Controversy Of Sufficient Immediacy And Reality

Lastly, Acuitas has not met its burden to show there is a substantial controversy of "sufficient immediacy and reality" to warrant the issuance of a declaratory judgment. Far from it, Defendants sent the two letters that Acuitas relies on to nonparties Pfizer/BNT nearly one year and two years ago, respectively. The later letter indicates that discussions regarding a potential license are ongoing, and Defendants have not filed any lawsuit against Pfizer/BNT in the time since, nor have Pfizer/BNT filed any suit against either Defendant. Acuitas has not alleged anything

suggesting that discussions regarding a potential license are at an end, such that a controversy may exist now even with Pfizer/BNT. Nor could Acuitas plead anything about the current state of these discussions because it is not privy to them. The alleged controversy here may never require judicial intervention, much less immediate judicial intervention.

2. Acuitas's Attempt To Rely On Its Alleged Supplier-Customer Relationship With Pfizer/BNT Fails To Establish Jurisdiction

Lacking any relevant contact between itself and Defendants regarding Comirnaty, Acuitas attempts to rely on its alleged supplier-customer relationship with Pfizer/BNT to establish standing. Dkt. 42, ¶ 22. Acuitas's reliance is misplaced because it fails to meet the Federal Circuit's controlling standards. In *Arris* the Federal Circuit explained that: "where a patent holder accuses customers of direct infringement based on the sale or use of a supplier's equipment, the supplier has standing to commence a declaratory judgment action if (a) the supplier ***is obligated to*** indemnify its customers from infringement liability, or (b) there is a controversy between the patentee and the supplier as to the supplier's liability for induced or contributory infringement based on the alleged acts of direct infringement by its customers." *Arris*, 639 F.3d at 1375.

Acuitas fails to meet this test: *First*, Acuitas does not allege that it has an actual obligation to indemnify Pfizer or BNT and instead even seems to dispute that. *Second*, as to indirect infringement, Acuitas does not show that Defendants have ever alleged that Acuitas meets any of the numerous legal elements required for claims of indirect infringement. *Third*, Acuitas cannot rely on the supplier-customer doctrine in any event because there is not even an actual controversy between Defendants and Pfizer/BNT as to direct infringement in the first place.

a. Acuitas's Indemnity Theory Fails To Establish Jurisdiction

Acuitas's indemnity-related theory fails to establish jurisdiction because ***the Amended Complaint does not allege that Acuitas is actually obligated to indemnify BNT (or Pfizer)***. To

the contrary, Acuitas avoids alleging that it is obligated to indemnify Pfizer/BNT for infringement, presumably to preserve its ability to disclaim any indemnification obligation if/when it serves Acuitas's interests to do so. Acuitas's pleadings, therefore, fail as a matter of law.

The Federal Circuit has instructed that a plaintiff-supplier must have an actual indemnity obligation for it to stand in the shoes of a customer and have standing to bring suit. *See Microsoft Corp. v. DataTern*, 755 F.3d 899, 904 (Fed. Cir. 2014) ("If Appellees had an obligation to indemnify their customers, they would then have standing to bring suit. In that instance, Appellees would stand in the shoes of the customers and would be representing the interests of their customers because of their legal obligation to indemnify. But here there is no evidence of such an obligation.") (internal citations omitted). Numerous courts applying *Microsoft* have found that "[a]bsent a 'clear, direct allegation' that a declaratory judgment plaintiff is obligated to indemnify its customers, a case or controversy does not exist based on an indemnity theory." *SynKloud Techs., LLC*, 484 F. Supp. 3d at 179; *see also Intel Corp. v. Future Link Sys., LLC*, No. 14-377, 2015 WL 649294, at *12 (D. Del. Feb. 12, 2015) ("In the absence of a clear, direct allegation that [supplier] is obligated to indemnify its customers with regard to [defendant's] accusations against them…the Court cannot find that [supplier] has demonstrated the existence of actual controversy.").

Acuitas's purported indemnity allegations are strategically noncommittal and thus fail as a matter of law. Specifically, Acuitas alleges that "BioNTech gave notice to Acuitas of a claim for indemnification" and that this is sufficient to establish jurisdiction regardless of "***[w]hether or not Acuitas ultimately would have indemnification obligations***." Dkt. 42, ¶ 26. Compounding the insufficiency of its indemnity allegations, Acuitas alleges that its license agreement with BNT

"contains indemnification provisions," without explanation of which party is obligated to indemnify, under what circumstances, or for what types of disputes. *Id*.

Acuitas's failure to allege that it has an actual indemnity obligation is particularly revealing because Defendants had already highlighted the insufficiency of Acuitas's indemnity allegations before Acuitas filed its Amended Complaint. Specifically, in Acuitas's July 8, 2022, letter to the Court it made similar noncommittal allegations regarding indemnity, Dkt. 34 at 3, and, in the August 1, 2022, joint letter to the Court, Defendants cited applicable caselaw requiring, as a matter of law, that an alleged indemnitor set forth in the complaint a clear, direct allegation that it is actually obligated to indemnify to establish standing. Dkt. 36 at 3. Yet in its Amended Complaint, Acuitas still did not allege that it actually has an indemnity obligation.

Absent an actual indemnity obligation and as the case law instructs, Acuitas does not stand in the shoes of Pfizer/BNT and does not represent their interests. Moreover, in the event that Acuitas successfully established that it in fact is not obligated to indemnify BNT or Pfizer for infringement, Acuitas's proffered basis for subject matter jurisdiction over this case would disappear. Accordingly, courts, applying *Microsoft,* have found allegations that preserve the right to later dispute the existence of an indemnity obligation to be insufficient to establish jurisdiction.

For example, in *Intel*, the court found the indemnity allegations deficient because the plaintiff-supplier was "careful not to commit to an answer to" the question of whether it was actually obligated to indemnify its customer. *Intel*, 2015 WL 649294 at *12. Ultimately, the *Intel* court found the plaintiff-supplier's allegations insufficient to establish an actual controversy because "a close read of [plaintiff's] allegations shows that ***they could be just as compatible with a future effort by [plaintiff] to deny any indemnity obligation as they would be with an***

acknowledgment that one exists." *Id*. Acuitas's pleadings are just as compatible with a future effort to deny any indemnity obligation as those in *Intel* and fail for at least the same reason.

Acuitas is also incorrect as a matter of law that a mere customer demand for indemnification is sufficient to establish subject matter jurisdiction. The Federal Circuit squarely rejected just this argument in *Microsoft*, where the plaintiff "argue[ed] that a customer request to indemnify ought to give rise to standing, without regard, it appears, to the merit of the request." *Microsoft*, 755 F.3d at 904. The Federal Circuit disagreed in no uncertain terms:

> Appellees seek to broaden our precedent quite substantially by arguing that a customer request to indemnify ought to give rise to standing, without regard, it appears, to the merit of the customer request. ***This cannot be. Thus, we decline Appellees' request to hold that their customers' indemnification requests, which they concede are not valid, alone can create standing and thus a basis for jurisdiction over Appellees' declaratory judgment actions.***

Id. Multiple courts, applying *Microsoft*'s instructions, have likewise rejected attempts by plaintiff-suppliers to premise subject matter jurisdiction on mere customer indemnity demands. *See BroadSign Int'l*, 2018 WL 357317, at *3 ("[R]equests for indemnification," without an allegation of plaintiff's "obligation to indemnify, do not suffice to support jurisdiction"); *SynKloud Techs., LLC*, 484 F. Supp. 3d at 179 ("A customer request to indemnify against patent infringement does not create subject matter jurisdiction."); *Proofpoint, Inc. v. InNova Pat. Licensing, LLC*, No. 5:11-CV-02288, 2011 WL 4915847, at *5 (N.D. Cal. Oct. 17, 2011) ("Without more, allegations of indemnity requests are not enough to find a 'substantial controversy.'").

Thus, Acuitas's indemnity allegations fail to establish jurisdiction as a matter of law.

b. Acuitas's Indirect Infringement Theory Fails To Establish Jurisdiction

Acuitas's second basis for relying on its alleged supplier-customer relationship with Pfizer/BNT, its indirect infringement theory, also fails. Acuitas cites Defendants' letters to Pfizer/BNT as establishing an actual controversy with respect to contributory infringement under

35 U.S.C. § 271(c) and induced infringement under 35 U.S.C. § 271(b). But under controlling Federal Circuit law as set forth in *Microsoft*, there is no actual controversy as to either.

(i) Defendants' Letters To Pfizer/BNT Do Not Create An Actual Controversy As To Contributory Infringement

For a patentee to establish contributory infringement by a component supplier, the patentee must show that four legal elements are met, including that (1) the supplier's product is "not a staple article or commodity of commerce suitable for substantial noninfringing use," and (2) the supplier knows that its product is especially made or especially adapted for use in an infringement of the relevant patent. 35 U.S.C. § 271(c). Accordingly, for a patentee's communication to create an actual controversy regarding contributory infringement with a supplier, the communication must meet at least both of the following requirements: *First*, the communication must contain allegations that suggest or imply that the supplier's product is "not a staple article or commodity of commerce suitable for substantial noninfringing use." *See Microsoft*, 755 F.3d at 906. *Second*, the communication must contain allegations that the supplier knew its product is especially made or especially adapted for use in an infringement of the relevant patent. *Id*. Here, Defendants' letters do not so much as mention Acuitas, much less include specific allegations as to whether Acuitas's lipids or LNPs have substantial uses other than in the vaccine or about Acuitas's knowledge in supplying them. The letters therefore do not create an actual controversy.

In the controlling *Microsoft* case, the supplier/declaratory judgment plaintiff (Microsoft) argued that claim charts the patentee had served on Microsoft's customers in a separate litigation created an actual controversy as to Microsoft's contributory infringement of the relevant patent, the '402 patent. *Id*. at 904–05. The Federal Circuit, however, found that the '402 patent claim charts did not establish an actual controversy as to contributory infringement for two reasons: 1) the claim charts did not include allegations that "imply or suggest that Microsoft's [product] is not

'a staple article or commodity of commerce suitable for substantial non-infringing use;'" and 2) the charts did not contain an allegation that "Microsoft knew that it['s product] was 'especially made or adapted for use in an infringement' of [defendant's] patents." *Id*. at 906. Applying the Federal Circuit's analysis in *Microsoft* here, Defendants' letters fail to create an actual controversy for at least the same reasons.

The SDNY's *BroadSign* opinion is also instructive. There, the court found there was no actual controversy as to contributory infringement because the plaintiff "failed to allege facts indicating that [defendant] could establish … that [plaintiff] 'knew its product was especially made or especially adapted for use in an infringement of the [Patents-in-Suit]' or that '[plaintiff's product] is not a staple article or commodity of commerce suitable for substantial noninfringing use." *BroadSign*, 2018 WL 357317, at *4. As in *Broadsign*, the Amended Complaint here does not allege facts indicating that Defendants could establish that Acuitas knew its lipids and LNP technology were especially made or especially adapted for infringement or that they are not staple articles or commodities of commerce. Thus, there is no actual controversy as to contributory infringement.

(ii) Defendants' Letters To Pfizer/BNT Do Not Create An Actual Controversy As To Inducement

Defendants' letters to Pfizer/BNT also do not create an actual controversy as to inducement because the letters do not allege that Acuitas is encouraging Pfizer/BNT to practice any limitation of the claims of Defendants' Patents. In fact, Defendants' letters do not mention Acuitas at all. *Microsoft* again provides the controlling legal standard. Under *Microsoft*, for Defendants' letters to have created an actual controversy as to inducement, they would have had to have identified Acuitas and specifically alleged that Acuitas is encouraging Pfizer/BNT to practice the limitations of the claims. *See Microsoft*, 755 F.3d at 905.

In *Microsoft*, the plaintiff-supplier (Microsoft) argued that the patentee's claim charts served on Microsoft's customers in separate litigation created an actual controversy with Microsoft regarding induced infringement. The patentee had served claim charts for two patents, the '502 patent and the '402 patent mentioned above. Addressing each patent in turn, the Federal Circuit found that the patentee's allegations in its claims charts for the '502 patent created an actual controversy as to Microsoft's potential inducement because these claim charts *identified Microsoft* and *cited to Microsoft documentation* to show that every claim limitation was satisfied. Thus, the court found that those claim charts "allege[d] that Microsoft is encouraging" the direct infringement. *Id*.

In important contrast, the Federal Circuit found that there was no actual controversy as to inducement created by the '402 patent claim charts because the claim charts for that patent did not identify Microsoft or cite to any Microsoft documents for several of the limitations of the asserted claims. Given the lack of mention of Microsoft for several limitations, the court found there was no allegation in the charts that Microsoft encouraged the customer to infringe, and thus no actual controversy as to inducement created by the '402 patent claim charts. *Id*.

Application of the Federal Circuit's analysis to Defendants' letters here is straightforward. Defendants' letters do not accuse Acuitas of encouraging Pfizer/BNT to practice the limitations of the claims of Defendants' Patents. Nor does Acuitas allege otherwise. Thus, there is no actual controversy as to inducement created by Defendants' letters.

Acuitas's allegation that by the time Defendants had sent their letters it was publicly known that Acuitas was supplying lipids and LNPs to Pfizer/BNT does not change the analysis or result. Dkt. 42, ¶ 12. Regardless of whether Defendants knew that Acuitas was supplying Pfizer/BNT with lipids or LNP technology, under *Microsoft* Defendants' letters to Pfizer/BNT *cannot* create

an actual controversy without specifically alleging that Acuitas encouraged Pfizer/BNT to practice the limitations of Defendants' Patents. *Microsoft* made this clear by finding no actual controversy as to inducement of the '402 patent, *even though the patentee knew the customers were using Microsoft's products* in the alleged infringement. The fact that the claim charts lacked any allegation that Microsoft encouraged the infringement was dispositive, irrespective of whether the patentee knew that the customers were using Microsoft's products. *Microsoft*, 755 F.3d at 905. Likewise, here, there is no actual controversy as to inducement because Defendants' letters do not allege Acuitas encourages Pfizer/BNT to infringe. Whether Defendants knew Pfizer/BNT were using Acuitas's lipids or LNP technology does not alter that result.

c. Acuitas's Supplier-Customer Argument Fails For The Separate Reason That There Is No Actual Controversy Between Defendants And Pfizer/BNT, So Acuitas Cannot Step Into Pfizer/BNT's Shoes To Defend Them

Acuitas's attempt to rely on the supplier-customer caselaw for jurisdiction fails for the separate and independent reason that Defendants' letters do not create an actual controversy between Defendants and Pfizer/BNT as to direct infringement in the first place. As a result, Acuitas's attempt to rely on doctrines that allow a supplier to step into the shoes of a customer fails to meet the prerequisite of a controversy between the patentee and the supplier's customers. *See Allied*, 870 F.3d at 1341 (instructing that the *Arris* test only applies where there are allegations of direct infringement against a customer).

Acuitas attempts to create an actual controversy from the letters to Pfizer/BNT by highlighting the 35 U.S.C. § 287(a) notice provisions[8] therein. But, as the Federal Circuit has held, merely because a letter includes a § 287(a) notice does not mean there is an actual controversy

[8] Section 287(a) requires patentees to provide such notifications to preserve the ability to seek certain damages in the event the patentee files a patent infringement suit in the future.

created. *SRI Intern., Inc. v. Advanced Technology Laboratories, Inc.*, 127 F.3d 1462, 1470 (Fed. Cir. 1997) ("[A]ctual notice [under 287(a)] may be achieved without creating a case of actual controversy."). Rather, courts are to evaluate the totality of the circumstances for any such notice.

Here, the totality of the circumstances includes BNT and Genevant's longstanding history of working together on LNP-related product research and development programs without any need for litigation and that the letters to Pfizer/BNT were not threatening cease and desist letters. The letters proposed "a constructive partnering discussion" in "a spirit of cooperation toward our common goal" of eradicating COVID-19, so that "Pfizer [could] benefit from Genevant scientists' extensive experience and expertise with the formulation and manufacture of LNP delivery systems." Ex. B. For example, Pfizer/BNT appeared to be confronted with LNP-related storage, transport, and manufacturing capacity challenges that could have benefited from collaboration with Genevant. As part of the requested discussions, Genevant said it "would also welcome discussing the terms of a nonexclusive license to Pfizer to use our intellectual property." *Id*.

The letters state that Pfizer and BNT "may" infringe Defendants' patents, which is far short of the types of accusations of infringement that the Federal Circuit has found to create an actual controversy as to infringement. For example, in *SanDisk*, the Federal Circuit held subject matter jurisdiction existed where the patentee had given the infringer "a detailed presentation which identified, on an element-by-element basis, the manner in which [patentee] believed each of [plaintiff's] products infringed the specific claims of each of [patentee's] patents." *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1382 (Fed. Cir. 2007). The patentee had also given the plaintiff "a packet of materials, over 300 pages in length, containing, for each of [patentee's] fourteen patents under discussion, a copy of the patent, reverse engineering reports for certain of [plaintiff's] products, and diagrams showing a detailed infringement analysis." *Id*. Here,

Defendants' letters include no analysis of infringement whatsoever, and certainly no element-by-element analysis.[9]

In sum, the letters do not create an actual controversy between Defendants and Acuitas's alleged customers, Pfizer/BNT. Therefore Acuitas's attempt to rely on doctrines allowing a supplier to defend customers when the customers have been sued for or accused of infringement is misplaced. But, even if Acuitas could somehow show the prerequisite of a controversy between Defendants and Pfizer/BNT, Acuitas's supplier-customer arguments would, as discussed above, fail for a lack of both an indemnity obligation and any indirect infringement allegations made by Defendants against Acuitas.

B. The Court Should Exercise Its Discretion To Decline To Hear Acuitas's Request For Declaratory Judgment

Even if Acuitas could show subject matter jurisdiction, the Court should use its discretion to decline to entertain this suit. *Commc'ns Test Design, Inc. v. Contec, LLC*, 952 F.3d 1356, 1361 (Fed. Cir. 2020) ("[A] district court has 'unique and substantial discretion in deciding whether to declare the rights of litigants.'"). Here, the Court should decline to exercise jurisdiction for two separate reasons.

First, the Court should decline to hear this suit because it serves no useful purpose due to the serious risk of a multiplicity of actions regarding the same vaccine and the same patents. If

[9] The Amended Complaint also relies on the fact that Defendants sent a letter to Moderna on November 23, 2020, and subsequently sued Moderna for patent infringement on February 28, 2022, apparently to support a self-serving conclusion that Defendants will sue Pfizer/BNT. Dkt. 42, ¶ 25. Acuitas ignores the facts that (1) unlike Pfizer/BNT, Moderna had initiated a years-long battle against Defendants' patents, having attempted to invalidate three of them before the Patent Trial and Appeal Board and Court of Appeals for the Federal Circuit prior to Defendants' filing suit against Moderna, *see ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364, 1367 (Fed. Cir. 2021), (2) over eight months have passed since the filing of that suit and Defendants have not filed any patent infringement suit against Pfizer/BNT, and (3) discussions with Pfizer/BNT regarding a potential license have not been terminated.

the Court were to determine in this action that Comirnaty infringes Defendants' Patents or that the patents are not invalid, Pfizer/BNT might on the very next day file an action for noninfringement and invalidity and attempt to argue that, as nonparties here, they are not bound or estopped by this Court's judgment. Why wouldn't they? It is an abuse of the privilege afforded litigants under the Declaratory Judgment Act to use it as a contrivance for creating the foreseeable possibility of a second wave of actions seeking the same relief unsuccessfully sought in the first instance. Acuitas should not be permitted to do so.

Second, the Court should decline to hear this suit for the additional reason that Acuitas seeks to adjudicate issues that may never require judicial intervention, particularly in light of the discussions between Genevant and Pfizer/BNT regarding a potential license. There is no need to burden the Court with Acuitas's premature action when the actual parties to the negotiation have not sought judicial intervention. The Federal Circuit has specifically instructed that "a court may take into account the pendency of serious negotiations to sell or license a patent in determining to exercise jurisdiction over a declaratory judgment action" because "the need for judicial relief is not as compelling as in cases in which there is no real prospect of a non-judicial resolution of the dispute." *EMC Corp. v. Norand Corp*., 89 F.3d 807, 814 (Fed. Cir. 1996) (overruled on other grounds). Should those negotiations ultimately not succeed, any litigation regarding Comirnaty and the LNP technology it uses will flow from those discussions between the actual parties to the negotiation. Here, where the very letters Acuitas relies on evidence ongoing discussions regarding a potential license, there is no compelling reason for judicial relief at this time.

VI. CONCLUSION

For the foregoing reasons, the Court should dismiss the Amended Complaint, with prejudice.

Dated: October 4, 2022

Respectfully submitted,

/s/ Raymond N. Nimrod
Raymond N. Nimrod
Isaac Nesser
Matthew D. Robson
QUINN, EMANUEL, URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York NY 10010
T: 212-849-7000

Kevin P.B. Johnson
QUINN, EMANUEL, URQUHART & SULLIVAN, LLP
555 Twin Dolphin Drive, 5th Floor
Redwood Shores, CA 94065
T: 650-801-5000

Sandra Haberny (*pro hac vice* granted)
QUINN, EMANUEL, URQUHART & SULLIVAN, LLP
865 S. Figueroa Street, 10th Floor
Los Angeles, CA 90017
T: 213-443-3000

Attorneys for Defendant Genevant Sciences GmbH

Daralyn J. Durie (*pro hac vice* granted)
Eric C. Wiener (*pro hac vice* granted)
DURIE TANGRI LLP
217 Leidesdorff Street
San Francisco, CA 94111
T: 415-362-6666

Kira A. Davis
DURIE TANGRI LLP
953 E. 3rd Street
Los Angeles, CA 90013
T: 213-992-4499

Attorneys for Defendant Arbutus Biopharma Corp.